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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,999	03/16/2001	David M. Neville	14028.0284U2	7991

36339 7590 04/01/2005

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,999

Applicant(s)

NEVILLE ET AL.

Examiner

G. R. Ewoldt, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 8, 18, 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 12/09/04 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 12/09/04, have been entered.

2. Claims 1, 2, 4, 8, 10, 12, 13, and newly added Claims 14 and 15 are being acted upon.

3. Applicant's amendment, remarks, and 1.132 declaration of Inventor Neville, filed 12/09/04, are acknowledged. In view of Applicant's amendment, the previous rejection under the first paragraph of 35 U.S.C. 112 of Claims 1, 2, 4, 8, 10, and 12 for the introduction of new matter into the claims has been withdrawn.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

A) the diphtheria toxin construct employed in the claims is disclosed only as a binding mutant diphtheria toxin construct in the specification.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 13 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for the treatment of diabetes comprising the administration of UCHT1-CRM9, an immunosuppressant, and pancreatic islet cells from a donor,

does not reasonably provide enablement for:

a method for the treatment of diabetes comprising the administration of an immunotoxin, an immunosuppressant, and

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pancreatic islet cells from a donor, for the reasons of record as set forth in the paper mailed 5/20/03 and maintained in the paper mailed 4/07/04.

Applicant has not traversed this rejection.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 4, 8, 10, 12, 13, and newly added Claims 14 and 15 stand/are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,103,235 (IDS), for the reasons of record as set forth in the paper mailed 5/20/03 and maintained in the paper mailed 4/07/04.

Applicant's arguments, filed 12/09/04, have been fully considered but are not found persuasive. Applicant argues that in view of the petition to correct priority (which was subsequently granted), the instant application claims priority to Application No. 08/439,409, now U.S. Patent No. 6,103,235, thus, the '235 patent is not available as prior art.

Applicant is advised that the instant claims are drawn to a method of treating diabetes (or a diabetic subject). The '235 patent does not teach a method of treating diabetes (or the diabetic subject of Claim 15). Neither does the '235 patent teach a method employing the diphtheria toxin of the instant claims (the patent discloses only the use of binding mutant diphtheria toxins). Accordingly, the instant claims are not granted the benefit of priority to the '409 application. The priority date of Claims 1, 2, 4, 8, 10, 12, 13, and newly added Claim 15 is the priority date of parent application 09/064,413, 4/22/98. Given the introduction of new matter into the claim, the priority date of newly added Claim 14 is the filing date of the instant application, 3/16/01.

9. Claims 1, 2, 4, 8, 10, 12, 13, and newly added Claims 14 and 15 stand/are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/32137 (1996, IDS), in view of Henretta

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et al. (1994, IDS), for the reasons of record as set forth in the paper mailed 5/20/03 and maintained in the paper mailed 4/07/04.

Applicant arguments, filed 12/09/04, have been fully considered but are not found persuasive. Applicant argues that given the new priority date, PCT/US96/05087 (WO 96/32137), cannot be used as prior art. See section 7 above regarding the denial of the benefit of priority.

10. The following are new grounds for rejection.

11. Claim 14 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, a method employing an "anti-CD3-diphtheria toxin immunotoxin".

Applicant argues that support for the claim can be found in original Claims 1 and 5-7, and at page 10, lines 14-16. Applicant is advised that the specification teaches monovalent and divalent anti-CD3 antibodies, but not the more generic anti-CD3 antibodies.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

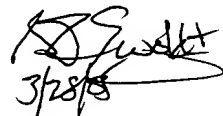
13. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the claim is vague and indefinite as it includes spelling errors (transplanting), grammatical errors (an a divalent immunotoxin), and nonsense errors (part (a)).

14. No claim is allowed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

16. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600